Remarks

Claims 57-62, 64-73, 75, and 77-79 are pending in the application and are presented for the Examiner's review and consideration. Claims 66 and 71 have been amended. Applicants believe that these claim amendments and the accompanying remarks serve to clarify the present invention and are independent of patentability. Accordingly, Applicants respectfully submit that that the claim amendments and remarks do not limit the range of any permissible equivalents.

The disclosure was objected to because of an informality. In response, Applicants have amended claim 71 as suggested by the Examiner and respectfully request withdrawal of this objection.

Claims 66 and 70 were rejected under 35 U.S.C. § 102(e) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,234,425 to Fogarty *et al.* ("Fogarty"). Claims 66 and 71 were rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,706,670 to Andersen *et al.* ("Andersen"). For the reasons set forth below, Applicants respectfully submit that these claims are not taught or suggested by Fogarty or Andersen.

Fogarty discloses a variable diameter sheath method and apparatus for use in body passages. A sheath 10 comprises a tubular braid 38 encapsulated within a coating 40 of high-elongation silicone polymer to provide an impermeable body 41. Fogarty, 3:65-68. The sheath 10 is elongate and proportioned to expand, when relaxed, to an outside diameter approximately equal to the inside diameter of the body passage within which the sheath is to be used. *Id.*, 3:27-32. In a typical embodiment, the sheath has an expanded relaxed diameter of from 6 to 7 mm and a contracted reduced diameter of 2 to 3 mm. *Id.*, 3:33-35. In short and as stated in Fogarty, "when in a passive state, the sheath assumes the expanded-diameter condition." *Id.*, 2:22-25.

The Examiner asserts that the Fogarty stent "is biased (outwardly) when it is in the contracted condition." As an alternative argument, the Examiner asserts that "the sheath 40 and filaments 42 are obviously resiliently expandable since sheath 40 is made of resilient material."

Applicants disagree with the Examiner's positions.

As disclosed, the Fogarty sheath is biased to the expanded condition. The sheath is contracted by use of a stylet to decrease the diameter of the sheath. Upon removal of the stylet, the sheath expands to its relaxed state, the expanded condition. Furthermore, with Fogarty, any object inserted through the sheath always contacts the sheath and not the braid as the braid is encapsulated by the sheath.

In contrast and as disclosed in the specification, a cannula 10 according to one embodiment of the present invention includes an expanding portion 12 with a plurality of wires 16 that are surrounded by an overlying elastic sheath 18. Specification, p. 7, lns. 15-20. The sheath 18 is of a diameter such that it is stressed even when the cannula is fully contracted. *Id.*, p. 8, ln. 27 to p. 9, ln. 1. "Thus the sheath 18 constantly biases the wires 16 radially inwardly toward the axis 22 of the cannula 10." *Id.*, p. 9, lns. 2-3. The specification further discloses:

> Thus, it is seen that the wires 16 have outer surface portions 60 disposed radially inwardly in the cannula 10 and forming contact surfaces for surgical instruments and the like inserted through the central instrument passage 20 of the cannula. The sheath 18 has an outer circumferential surface 54 engaging tissue when the cannula 10 is in use. The wires 16 block engagement of instruments inserted through the central instrument passage 20 of the cannula 16 with the elastic sheath 18. The sheath 18 blocks engagement of tissue with the wires 16, and the sheath and the wires block engagement of tissue with any instruments inserted through the cannula 10. *Id.*, p. 13, lns. 3-13.

In order to clarify the present invention, claim 66 now recites a cannula comprising a tubular sheath which at least partially encloses an array of filaments which extends between axially opposite end portions of said sheath substantially from one end portion to the other end portion of said sheath, said sheath having a passage configured and dimensioned to receive an object therethrough and which extends between opposite end portions of said sheath with said array of filaments extending along an inner side of said passage such that said array of filaments inhibits contact between an object inserted in the passage and said sheath. Claim 66 further recites that the sheath is biased inwardly to the

contracted condition.

With respect to the alternate obviousness rejection, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness. As noted above, Fogarty does not teach or suggest all of the claim elements. Additionally, there is no motivation or suggestion to modify the reference. Fogarty expressly teaches against the sheath being biased in the contracted state. Specifically, Fogarty discloses that the sheath has an expanded relaxed diameter of from 6 to 7 mm, and a contracted reduced diameter of 2 to 3 mm. Fogarty, 3:33-35. This is further supported by independent claims 1, 12, and 20 which all include the element "is expandable to a relaxed outside diameter."

Furthermore, there is no reasonable expectation of success found in Fogarty. Fogarty discloses elongation of the sheath to contract its tubular body is provided by extending the stylet 36 through the sheath to a compression imparting connection adjacent the distal end. *Id.*, 4:54-57. The sheath is expanded by disengaging and withdrawing the stylet fully from the sheath, thus relaxing the sheath for expansion. *Id.*, 5:17-19; 46-49. There is no disclosure for expansion of a sheath biased inwardly in a contracted condition.

In light of the foregoing, independent claim 66 is respectfully submitted to be patentable over Fogarty. As claim 70 depends from claim 66 and necessarily includes all the elements of its base claim, Applicants respectfully submit that claim 70 is also allowable over Fogarty at least for the same reasons.

As previously noted, the Examiner also rejected independent claims 66 as anticipated by, or in the alternative, as obvious over Andersen.

Andersen discloses a balloon catheter having a balloon portion I, a moving portion II, and an immovable portion III. Andersen, 5:16-22. The distal end 25 of the catheter 4 of FIG. 4(a) has a tapered, hollow plastic tip 22 to which distal end 24 of the inner catheter tube 26 is sealed. *Id.*, 5:27-29. Inner tube 26 is made of a polytetraflouroethylene plastic having an outside diameter of 0.72 mm and an inside diameter of 0.50 mm through which a guide wire having a diameter of about 0.015 mm may be passed. *Id.*, 5:27-33. As shown in FIG. 4(a) the balloon has

been expanded by the application of pressure to the fluid space between the inner wall of the catheter shaft 4 and the outer surface of the inner tube 26. *Id.*, 5:34-38. Fitting 40 includes a central opening 41 for a guide wire which is connected via a central passageway 42 to a central lumen 43 in inner tube 26 and thence to and out of tip 22. *Id.*, 5:65-68.

The Andersen catheter has three portions, only one of which is expandable, the balloon portion I. The balloon portion I is expandable with the application of pressure to the fluid space between the inner wall of the catheter shaft and the outer wall of the inner tube. The fluid space does not provide a passage through the catheter, as the distal end of the catheter is sealed to the distal ended of the inner tuber. The passage through the catheter is provided through the inner tube, which has a fixed inner and outer diamcter.

In contrast, one embodiment of the present invention relates to a cannula 10 that is expanded radially outwardly to thereby make a larger central passage 20 for instruments along its entire length. Specification, p. 11, lns. 15-21. The cannula 10 expands radially outwardly along substantially its entire length against the bias of the sheath 18. *Id.*, p. 13, lns. 15-17. Thus, the cannula 10 can accommodate through its central instrument passage 20 a surgical instrument or the like having a diameter along its entire length which is greater than the diameter of the cannula in the contracted condition. *Id.*, p. 13, lns. 17-21. This is not possible with cannulas which expand only along a portion of their length. *Id.*, p. 13, lns. 21-22. It is also not possible with Andersen since the only structure on Andersen that expands is the interior of the balloon and this is a sealed system incapable of receiving any object.

In order to clarify the invention claimed in claim 66, claim 66 now recites that has been amended to recite that the expandable cannula includes a sheath having a passage which extends between opposite end portions of said sheath and is configured and dimensioned to receive an object therethrough. Claim 66 further recites that the passage, like the sheath and array of filaments, resiliently expands from a contracted condition in which the passage has a relatively small cross sectional size in a plane perpendicular to a longitudinal central axis of the sheath to an expanded condition in which the passage has a relatively large cross sectional size. As noted

above, in Andersen, the fluid space between the inner surface of the catheter and the outer surface of the inner tuber is not a passage, as the distal end portions of the catheter and inner tuber are sealed together. The only passage defined in Andersen is through the inner tube, which has a fixed inner and outer diameter.

With respect to the alternate obviousness rejection, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness. As noted above, Andersen does not teach of suggest all of the claim elements. Additionally, there is no motivation or suggestion to modify the reference. Andersen expressly teaches against the passage being expandable. Specifically, the inner tube 26 of Andersen is made of a polytetraflouroethylene plastic having an outside diameter of 0.72 mm and an inside diameter of 0.50 mm through which a guide wire having a diameter of about 0.015 mm may be passed. Andersen, 5:27-33. This is further supported that fact that the only portion of the catheter that is described as being expandable is the balloon portion I. An expandable passage would necessitate the movable portion II and the immovable portion II being expandable as well, which is expressly taught against.

In light of the foregoing, independent claim 66 is respectfully submitted to be patentable over Andersen. As claim 71 depends from claim 66 and necessarily include all the elements of its base claim, Applicants respectfully submit that claim 71 is also allowable over Andersen at least for the same reasons.

Claims 67-69 were objected to as being dependent upon a rejected base claim. As noted above, Applicants submit that claim 66 is in condition of allowance. As claim 67-69 depend from claim 66 and necessarily include all the elements of the base claim, Applicants hereby respectfully request reconsideration and withdrawal of the objection.

Finally, Applicants acknowledge with appreciation the continued allowance of claims 57-62, 64, 65, 72, 73, 75, and 77-79.

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this

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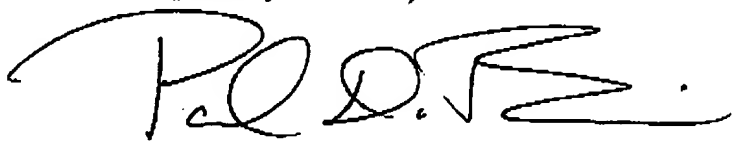
Application No.: 09/992,211
Examiner: M. Thaler

amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due with this submission. However, please charge the required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 780-A02-003-2).

Respectfully submitted,



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